CENTERS FOR DISEASE CONTROL AND PREVENTION

Press Release

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CDC Media Relations
Phone: (404) 639-3286

CDC's Advisory Committee Recommends New Vaccine to Prevent Rotavirus Today

Rotavirus is the leading cause of gastroenteritis in infants and young children in the United States and worldwide**.**

The Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and Prevention (CDC) in their meeting in Atlanta today voted to recommend a newly licensed vaccine to protect against rotavirus, a viral infection that can cause severe diarrhea, vomiting, fever and dehydration (gastroenteritis) in infants and young children.

The ACIP recommendation is for infants to receive three doses of the oral vaccine at two, four, and six months of age. Children should receive the first dose of the vaccine by 12 weeks of age and should receive all doses of the vaccine by 32 weeks of age. There is insufficient data on safety and efficacy outside of these age ranges. The new vaccine, RotaTeq™ (marketed by Merck and Company), is the only vaccine approved in the United States for prevention of rotavirus gastroenteritis (vomiting and diarrhea).

"Rotavirus is the leading cause of severe gastroenteritis in infants and young children worldwide" said Dr. Anne Schuchat, director of CDC's National Immunization Program. "Nearly every child in the United States is infected with rotavirus by age five and most will develop gastroenteritis, leading to a large number of physician visits, emergency room visits, and hospitalizations, with a few deaths. Therefore, this vaccine will help reduce one of our most common and potentially severe childhood illnesses."

Each year, rotavirus is responsible for more than 400,000 doctor visits, more than 200,000 emergency room visits, 55,000 to 70,000 hospitalizations, and between 20 and 60 deaths in US children younger than 5 years of age, leading to about $300 million in direct medical costs and $900 million in total societal costs. In developing countries, rotavirus is a major cause of childhood deaths, causing more than half a million deaths each year in children younger than five years of age.

Rotavirus vaccine will not prevent gastroenteritis caused by other viruses, but is very effective against rotavirus disease. Studies indicate the vaccine will prevent about 74 percent of all rotavirus cases and about 98 percent of the most severe cases, including 96 percent of rotavirus cases requiring hospitalization. In trials, the vaccine prevented 59 percent of all causes of gastroenteritis hospitalizations, which highlights the important role of rotavirus in severe

childhood gastroenteritis.

In 1999, RotaShield®, a different rotavirus vaccine was withdrawn from the market after it was found to be associated with a rare type of bowel obstruction called intussusception. The risk of intussusception for RotaTeq™, the new vaccine, was evaluated in a large scale trial of over 70,000 children. In that study, there was no association found between the RotaTeq™ and an increased risk of intussusception and it did not cause fever to the extent caused by RotaShield®

"This is a different vaccine than the vaccine removed from the market because of problems with bowel obstructions," said Dr. Schuchat. "It is made differently and was not associated with intussusception in a large clinical trial. Nevertheless, we will continue to very closely monitor this vaccine to ensure there are no problems. At the same time it's important to remember that the known benefits of the vaccine far outweigh any known risks."

CDC will conduct a large study to rapidly detect any association between RotaTeq™ and intussusception as well as other potential adverse events through its Vaccine Safety Datalink Program that evaluates vaccine safety in approximately 90,000 infants every year. CDC and FDA will also regularly monitor reports of intussusception and other serious adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). Merck has also committed to conducting a post-licensure study of approximately 44,000 children. In addition, the manufacturer will report cases of intussusception to FDA within 15 days of receiving them.

Recommendations of the ACIP become recommendations of CDC once they are accepted by the director of CDC and the Secretary of Health and Human Services and are published in the *Morbidity and Mortality Weekly Report*.

For more information on rotavirus and the rotavirus vaccine, visit www.cdc.gov .

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